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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,080	08/30/2001	Carlo Effenhauser	RDID01056US	7687

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER
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SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/943,080

Applicant(s)

EFFENHAUSER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-40 is/are allowed.
- 6) ☒ Claim(s) 24-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Allowable Subject Matter***

1. The indicated allowability of claims 24-33 is withdrawn in view of the newly discovered reference(s) to Perez et al (2002/0103499 A1) and Effenhauser (6,572,566 B2). Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 24, 25, 28 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Perez et al (2002/0103499 A1).

Perez et al disclose a lancet having capillary action and further disclose a lancing unit configured to couple to a drive unit; the lancing unit comprising a detection zone configured to analyze the body fluid; a capillary structure having a lancing tip configured to cut an incision in the skin, the lancing tip defining a capillary groove for drawing the body fluid from the incision to the detection zone via capillary action, wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit collection of the body fluid along the length of the lancing tip; the drive unit is coupled to the lancing unit; the capillary structure includes a pair of needles joined together; the

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capillary structure includes a solid needle with a capillary groove defined therein; the detection zone includes an optical detector for analyzing body fluid; the detection zone includes an electrochemical detector for analyzing body fluid; the lancing tip has a distal end that initially contacts the skin during lancing; and the capillary groove further opens at the distal end of the lancing tip. See Figures 4A, 4C, 4F and 7.

4. Claims 24-26, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Effenhauser (6,572,566 B2).

Effenhauser discloses a means for measuring analyte concentration in body fluids and further disclose a lancing unit configured to couple to a drive unit; the lancing unit comprising a detection zone configured to analyze the body fluid; a capillary structure having a lancing tip configured to cut an incision in the skin, the lancing tip defining a capillary groove for drawing the body fluid from the incision to the detection zone via capillary action, wherein the capillary groove opens longitudinally along the outside of the lancing tip to permit collection of the body fluid along the length of the lancing tip; the drive unit is coupled to the lancing unit; the lancing unit includes a holding area in which a portion of the capillary structure is arranged; the holding area has a distal end from where the lancing tip extends and a top surface; the capillary groove opens along the top surface of the holding area; the capillary structure includes a solid needle with the capillary groove defined therein; and the detection zone includes an electrochemical detector for analyzing the body fluid. See Figure 1A; Column 8, lines 10-25.

***Claim Rejections - 35 USC § 103***

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al (2002/0103499 A1) as applied to claim 24 above, and further in view of Eriksen (2,359,550).

Perez et al, as discussed above, disclose a lancing device, but fail to disclose the capillary structure includes a stranded wire with a capillary groove formed between adjacent wires.

Eriksen discloses a lancing device and further disclose the capillary structure includes a stranded wire with a capillary groove formed between adjacent wires. See Figure 1.

Since both Perez et al and Eriksen disclose lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancing structure of Perez et al to include the use of a stranded wire lancing means, as per the teachings of Eriksen, since it would provide another means of lancing the skin with a capillary structure for obtaining a fluid sample.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Effenhauser (6,572,566 B2) as applied to claim 26 above, and further in view of Yassinzadeh et al (5,700,695).

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Effenhauser, as discussed above, disclose a lancing means for detecting analytes in body fluid, but fail to disclose the lancing unit includes a plate capping the holding area; the plate covers a portion of the capillary groove; and the plate defines a window over the detection zone.

Yassinzadeh et al disclose a sample collection means and further disclose the lancing unit includes a plate capping the holding area; the plate covers a portion of the capillary groove; and the plate defines a window over the detection zone. See Figure 12.

Since both Effenhauser and Yassinzadeh et al disclose lancing means for detecting analytes in a body fluid, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancing means of Effenhauser to include the use of a plate that defines a window over the detection zone, as per the teachings of Yassinzadeh et al, since it would provide direct access to the acquired sample for analysis.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Effenhauser (6,572,566 B2) as applied to claim 24 above, and further in view of Perez et al (2002/0103499 A1).

Effenhauser, as discussed above, disclose a lancing means for detecting analytes in a body fluid, but fail to disclose an optical detector for analyzing the body fluid.

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Perez et al, as discussed above, disclose a lancing means for obtaining a body fluid sample for analysis and further disclose an optical detector for analyzing the body fluid. See Paragraph 0081.

Since Effenhauser discloses the lancing unit can be used with analytical units but does not explicitly disclose the use of an optical analysis unit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an optical detector, as per the teachings of Perez et al, in combination with the lancing unit of Effenhauser.

***Allowable Subject Matter***

9. The following is a statement of reasons for the indication of allowable subject matter: Claim 34 is allowable since no prior art could be found teaching or suggesting a lancing apparatus comprising a holding area having an open capillary groove, the capillary groove opening along the surface of the holding area from the distal end of the lancing tip to the detection zone for transporting the body fluid via capillary action to the detection zone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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